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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,609	07/25/2003	Etsuko Matsunaga	240944US0	9357

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EXAMINER	
FOX, DAVID T	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,609	MATSUNAGA ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25* is/are allowed.

6)☒ Claim(s) *6-24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 02 November 2006 have obviated the indefiniteness rejection of record.

Indefiniteness

Claims 10-11 (newly amended) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-11 are indefinite in their recitation of "said selectable marker polynucleotide synthesizes the auxin [or auxin analogue] precursor" which fails to further limit claim 6. Claim 6 recites that the selectable marker polynucleotide encodes an enzyme that synthesizes auxin [or an auxin analogue] from an auxin [or auxin analogue] precursor". Claim 6 does not recite that the selectable marker polynucleotide synthesize the precursor itself.

Written Description

Claims 6-11 and 13-24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-5 of the last Office action.

Applicant's arguments filed 02 November 2006 have been fully considered but they are not persuasive. Applicant urges that the specification describes two selectable marker genes, namely the *iaaH* and *iaaM* genes; that the state of the art was well-developed so that the written description rejection is improper per *Capon v. Eshhar*; and that the genus of suitable genes is well-described per Woodward et al, appended to the Response of 02 November 2006.

The Examiner maintains that the *iaaM* gene, which is *directly involved* in the *synthesis* of an auxin *precursor*, is explicitly excluded by claims 6 and 25. Thus, the specification only describes one species of the genus of functional selectable marker genes which encode an enzyme which *synthesizes auxin* (or an auxin analogue) *from an auxin* (or auxin analogue) *precursor*.

Regarding *Capon*, the Examiner maintains that different fact patterns are involved in the instant application. In *Capon*, the claims encompassed the well-developed antibody art, wherein "over 785 mouse antibody DNA light chains and 1,327 mouse antibody DNA heavy chains were known and published as early as 1991" (see page 10 of *Capon* decision). In the instant case, the claims encompassed the unpredictable expression of auxin metabolism genes in plant cells transformed therewith, and the use of said genes as selectable markers for the production of whole transformed plants.

Regarding Woodward et al, the Examiner notes that the reference teaches that the auxin metabolism pathway is not completely understood, and that there are many unknown enzymes (and genes encoding them); per page 713, Figure 3, see the

question marks above or below the arrows. Woodward et al also teach that the genus of enzymes involved in auxin biosynthesis is large (see, e.g., page 710, Table 1; page 711, Figure 2; and page 713, Figure 3). However, neither Woodward et al nor Applicant's specification provide any guidance regarding the conserved structural features (i.e. sequence domains) associated with the function of acting as a viable selectable marker gene for the regeneration of viable transformed plants.

Enablement

Claims 6-24 remain, and new claim 26 is, rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method for producing a transgenic plant comprising transforming a plant cell with an *iaaH* gene and an *ipt* gene, culturing the plant cell on a medium comprising indoleacetamide or naphthalene acetamide, selecting transformed plant cells based on their ability to produce shoots on said medium, and regenerating a whole transformed plant therefrom; does not reasonably provide enablement for claims broadly drawn to the use of any gene encoding any enzyme which synthesizes an auxin from any precursor, the use of any non-exemplified auxin precursor as a selection agent, the use of an *iaaM* gene, or the omission of the *ipt* gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 6-9 of the last Office action.

Applicant's arguments filed 02 November 2006 have been fully considered but they are not persuasive. Applicant urges that the claims do not encompass a large

number of species of auxin biosynthesis genes, that such genes are in fact well-known per Woodward et al, that some inoperative embodiments are permissible, and that the art cited by the Examiner is unpersuasive due to its inapplicability or the subsequent advances in the art which have overcome any difficulties originally observed.

The Examiner maintains that Woodward et al teach that the genus is quite large, albeit not completely characterized, as discussed above.

Regarding the inoperable embodiments, the specification itself, as well as the art cited by the Examiner, teaches that at least half of the two disclosed species (namely the *iaaM* gene) would not work. Thus, the claims read on a majority of inoperative embodiments, which is impermissible per *Atlas Powder*.

See *Atlas Powder v. DuPont*, 224 USPQ 409, 414 (Fed. Cir. 1984), where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation.

Regarding the art cited by the Examiner to support his position, it is maintained that the general teachings of unpredictability inherent in the regeneration of whole transgenic plants, as taught by Budar and Prinsen, is eminently applicable to the instantly claimed method which requires said regeneration, whether or not Budar or Prinsen envisioned such a method.

Regarding the alleged solutions to the problems cited by Sitbon or Dpicker, namely promoter choice or negative selection, the Examiner maintains that the instant specification is entirely silent with regard to either of these concepts.

See *Genentech, Inc. v. Novo Nordisk*, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Conclusion

The claims remain free of the prior art, as stated in the last Office action.

Claim 25 is allowable.

The following amendments would result in allowance of the application:

Cancel claims 6, 8, 10-14, and 16.

Change the dependencies of claims 7, 9, 15 and 17-24 from claim 6 to claim 26.

Amend claim 26 as follows:

---Claim 26 (currently amended). A method for producing a transgenic plant, comprising:

(A) transforming a plant cell with a gene introduction vector which comprises:

a desired polynucleotide sequence, [and]

a selectable marker polynucleotide comprising an *iaaH* gene which encodes indoleacetamide hydrolase; and

an *ipt* gene encoding isopentenyl transferase;

(B) culturing the transformed plant cell described in (A) in a medium containing [the auxin precursor and/or auxin analog precursor] indoleacetamide or naphthaleneacetamide that is hydrolyzed into the auxin indoleactic acid (IAA) or the auxin analog naphthaleneacetic acid (NAA) [an auxin or auxin analog] by

indoleacetamide hydrolase, under conditions suitable for production of a redifferentiated plant tissue expressing said desired polynucleotide sequence and said selectable marker polynucleotide from said transformed plant cell,

(C) detecting and selecting the redifferentiated plant tissue described in (B), and

(D) culturing the redifferentiated plant tissue described in (C) into a transgenic plant comprising said desired polynucleotide sequence.---

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 17, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638